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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,607

07/20/2005

Satoru Hashimoto

J2000-7001US

1117

37462

7590

07/17/2006

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EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/524,607	<b>Applicant(s)</b> HASHIMOTO ET AL.	
	<b>Examiner</b> Laura A. Bouchelle	<b>Art Unit</b> 3763	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 July 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 12-17 is/are rejected.
- 7) ☒ Claim(s) 10 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/17/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 7-9, 12, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Inoue et al (US 6231539). Inoue discloses a backflow prevention valve in an injection device comprising a first fluid path 51a, a second fluid path 53a, a housing 51b having a larger cross section than the fluid paths, and a valve member 52. See Figs. 11a, 11b. The valve is made of a silicon rubber (Col. 14, line 58).

### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue in view of Mikhail et al (US 5624395). Claim 4 differs from Inoue in calling for the communication

portion of the valve to be concave. Claim 5 calls for the projection portion to be hemispherical in shape. Claim 6 calls for the cavity portion to be hemispherical in shape. Mikhail teaches a catheter having a valve with a concave portion and a hemispherical cavity because this configuration prevents an aliquot of liquid from being trapped in the cavity instead of draining through the valve opening (Col. 12, lines 35-50). See Fig. 9. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Inoue to have a concave valve forming a hemispherical cavity as taught by Mikhail to prevent an aliquot of liquid from being trapped in the cavity instead of draining through the valve opening.

5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue. Where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. See MPEP 2144.04. Although Inoue does not disclose the dimensions of the housings, one of ordinary skill in the art would expect the device to perform with the recited dimensions. ✓

6. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue in view of Kurth et al (US 5792118). Claim 15 differs from Inoue in calling for the valve to be opened by a pressure of below 0.2 Kgf/cm<sup>2</sup>. Kurth teaches a catheter having a valve where the opening pressure is less than 3 psi (2.1 Kgf/cm<sup>2</sup>) to maintain the required flow rate through the valve (Col. 1, lines 44-46). Therefore, it would have been obvious to one of ordinary skill in the art at

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the time of invention to modify the device of Inoue to have the valve opened by a force of less than 2 Kg/cm<sup>2</sup> as taught by Kurth to maintain the required flow rate.

7. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US 6290681) in view of Inoue. Brown discloses a drug supply line having a drug supply means 84, a tubular member, a drug administering means 80, a transducer for measuring the pressure inside the tube and a pressure value display (Col. 2, lines 30-55). Claim 16 differs from Brown in calling for the valve of claim 1. Inoue teaches the valve of claim 1 as discussed above to prevent back flow of liquid (See Abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Brown to include the valve of Inoue to prevent backflow in the device.

### ***Claim Objections***

8. Claims 10 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

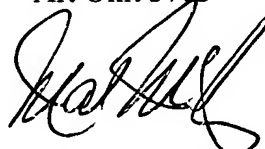
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LAB

Laura A Bouchelle  
Examiner  
Art Unit 3763



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